ephedrine together with a therapeutically significant quantity of another active medicinal ingredient.

(b) An application for an exemption under this section shall contain the following information:

(1) The name and address of the applicant;

(2) The exact trade name of the drug product for which exemption is sought;

(3) The complete quantitative and qualitative composition of the drug product;

(4) A brief statement of the facts which the applicant believes justify the granting of an exemption under this section; and

(5) Certification by the applicant that the product may be lawfully marketed or distributed under the Food, Drug, and Cosmetic Act.

(6) The identification of any information on the application which is considered by the applicant to be a trade secret or confidential and entitled to protection under U.S. laws restricting the public disclosure of such information by government employees.

(c) The Administrator may require the applicant to submit such additional documents or written statements of fact relevant to the application which he deems necessary for determining if the application should be granted.

(d) Within a reasonable period of time after the receipt of a completed application for an exemption under this section, the Administrator shall notify the applicant of acceptance or non-acceptance of the application. If the application is not accepted, an explanation will be provided. The Administrator is not required to accept an application if any of the information required in paragraph (b) of this section or requested pursuant to paragraph (c) of this section is lacking or not readily understood. The applicant may, however, amend the application to meet the requirements of paragraphs (b) and (c) of this section. If the application is accepted for filing, the Administrator shall issue and publish in the FEDERAL REGISTER an order on the application, which shall include a reference to the legal authority under which the order is based. This order shall specify the date on which it shall take effect. The Administrator shall permit any interested person to file written comments on or objections to the order. If any comments or objections raise significant issues regarding any findings of fact or law upon which the order is based, the Administrator shall immediately suspend the effectiveness of the order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, revoke, or amend the original order as deemed appropriate.

[60 FR 32462, June 22, 1995, as amended at 62 FR 13968, Mar. 24, 1997]

§ 1310.15 Exempt drug products containing ephedrine and therapeutically significant quantities of another active medicinal ingredient.

(a) The drug products containing ephedrine and therapeutically significant quantities of another active medicinal ingredient listed in paragraph (e) of this section have been exempted by the Administrator from application of sections 302, 303, 310, 1007, and 1008 of the Act (21 U.S.C. 822–3, 830, and 957–8) to the extent described in paragraphs (b), (c), and (d) of this section.

(b) No exemption granted pursuant to 1310.14 affects the criminal liability for illegal possession or distribution of listed chemicals contained in the exempt drug product.

(c) Changes in drug product compositions: Any change in the quantitative or qualitative composition of an exempt drug product listed in paragraph (d) requires a new application for exemption.

(d) In addition to the drug products listed in the compendium set forth in §1310.01(b)(28)(i)(D)(*1*), the following drug products, in the form and quantity listed in the application submitted (indicated as the ''date'') are designated as exempt drug products for the purposes set forth in this section:

EXEMPT DRUG PRODUCTS CONTAINING EPHEDRINE AND THERAPEUTICALLY SIGNIFICANT QUANTITIES OF ANOTHER ACTIVE MEDICINAL INGREDIENT

Supplier	Product name	Form	Date
[Reserved]	.....	.....	

[60 FR 32463, June 22, 1995, as amended at 62 FR 13968, Mar. 24, 1997]

PARTS 1311 [RESERVED]

PART 1312—IMPORTATION AND EXPORTATION OF CONTROLLED SUBSTANCES

Sec.

AUTHORITY: 21 U.S.C. 952, 953, 954, 957, 958.

SOURCE: 36 FR 7815, Apr. 24, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

§ 1312.01 Scope of part 1312.

Procedures governing the importation, exportation, transshipment and intransit shipment of controlled substances pursuant to section 1002, 1003, and 1004 of the Act (21 U.S.C. 952, 953, and 954) are governed generally by those sections and specifically by the sections of this part.

§ 1312.02 Definitions.

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

[62 FR 13969, Mar. 24, 1997]

IMPORTATION OF CONTROLLED SUBSTANCES

§ 1312.11 Requirement of authorization to import.

(a) No person shall import or cause to be imported any controlled substance listed in Schedule I or II or any narcotic controlled substance listed in Schedule III, IV or V or any non-narcotic controlled substance in Schedule III which the Administrator has specifically designated by regulation in §1312.30 of this part or any non-narcotic controlled substance in Schedule IV or V which is also listed in Schedule I or II of the Convention on Psychotropic Substances unless and until such person is properly registered under the Act (or exempt from registration) and the Administrator has issued him a permit to do so pursuant to §1312.13 of this part.

(b) No person shall import or cause to be imported any non-narcotic controlled substance listed in Schedule III, IV or V, excluding those described in paragraph (a) of this section, unless and until such person is properly registered under the Act (or exempt from registration) and has filed an import declaration to do so with the Administrator, pursuant to §1312.18 of this part.

(c) When an import permit or declaration is required, a separate permit or declaration must be obtained for